



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Draft Five-Year Plan (2013-2017) for the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods and the Interagency Coordinating Committee on the Validation of Alternative Methods

AGENCY: Division of National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Availability of Draft Plan, Request for Comments

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) has developed a draft NICEATM–ICCVAM Five-Year Plan. The plan describes four core strategies to foster and promote development, validation, and regulatory acceptance of scientifically sound alternative test methods by the Federal government and by other governments and multinational organizations. This document will provide strategic direction for NICEATM and ICCVAM during 2013–2017.

NIEHS and NICEATM request public comments on the draft 2013-2017 Five-Year Plan, which is available at <http://iccvam.niehs.nih.gov/docs/5yearplan.htm>. NICEATM and ICCVAM in partnership with relevant agency program offices will consider these comments during development of the final plan.

DATES: The draft plan is available on the NICEATM–ICCVAM website at <http://iccvam.niehs.nih.gov/docs/5yearplan.htm>. Written comments on the draft updated NICEATM–ICCVAM Five-Year Plan should be submitted on the website by [insert date 60 days after publication date].

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2–16, Research Triangle Park, NC, 27709, (telephone) 919–541–2384, (fax) 919–541–0947, (email) niceatm@niehs.nih.gov. Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

Emerging scientific advances and technology innovations are driving transformative changes in toxicology and how safety testing is performed. The field of toxicology is evolving from a system based largely on animal testing toward one based on the integration of data from a wide range of sources, including *in vitro* methods that evaluate changes in biological pathways predictive of adverse outcomes and *in chemico* and *in silico* methods.

Congress established ICCVAM to promote the regulatory acceptance of new or revised scientifically valid toxicological test methods that protect human and animal health and the environment while reducing, refining (enhancing animal well-being and lessening or avoiding pain and distress), or replacing animal tests and ensuring human safety and product effectiveness. As directed by the ICCVAM Authorization Act (42 U.S.C. 285l–3), NICEATM and ICCVAM carry out activities that contribute to the

validation and regulatory acceptance of new test methods and testing strategies.

In 2008, NICEATM and ICCVAM published the NICEATM-ICCVAM Five-Year Plan (2008-2012), which addressed ICCVAM's vision to play a leading role in fostering and promoting the development, validation, and regulatory acceptance of scientifically sound alternative test methods both within the Federal government and internationally (ICCVAM, 2008). NICEATM and ICCVAM have now prepared a draft plan to provide strategic direction for NICEATM and ICCVAM in accomplishing their purposes, duties, and mission for the years 2013-2017. In preparing this plan, NICEATM and ICCVAM considered information and comments submitted by member agencies and comments submitted in response to a **Federal Register** notice (76 FR 71977).

The draft plan outlines how, consistent with ICCVAM's statutory duties and purposes, NICEATM and ICCVAM will foster and promote the incorporation of scientific advances and innovative technologies into new improved test methods and strategies, and contribute to the transformation of toxicology. The draft plan describes four broad strategic opportunities for NICEATM and ICCVAM to foster and promote development, validation, and regulatory acceptance of scientifically sound alternative test methods by the Federal government and other organizations:

- *Promote the Application and Translation of Innovative Science and Technology* to develop predictive alternative test methods and efficient and predictive integrated testing and decision strategies (ITDS)
- *Advance Alternative Test Methods and Testing Strategies* through new evaluation activities for focus areas initially identified in the 2008-2012 Five-Year Plan and new focus areas for 2013-2017

- *Facilitate Regulatory Acceptance and Use of Alternative Methods* through high quality test method evaluations and effective outreach and communication
- *Develop and Strengthen Partnerships* with the broad range of ICCVAM stakeholders

The years 2013–2017 will be an essential transition period for NICEATM and ICCVAM in this transforming regulatory toxicology environment. For example, data from *in vitro* testing batteries and integrated decision strategies that consider all available information from *in chemico*, *in silico*, *in vitro*, and/or *in vivo* studies will be critical to regulatory decision-making in the future.

Request for Comments

NIEHS and NICEATM invite public comments from all ICCVAM stakeholders for consideration by ICCVAM and ICCVAM agencies' program offices on the draft 2013–2017 Five-Year Plan. The draft plan can be found on the NICEATM–ICCVAM website at <http://iccvam.niehs.nih.gov/docs/5yearplan.htm>. In addition, comments are sought on how NICEATM and ICCVAM can most effectively contribute to the evolving transformation of safety testing. Stakeholder comments will be considered in finalization of the draft plan.

NICEATM prefers that comments be submitted electronically via a form on the NICEATM–ICCVAM website at <http://iccvam.niehs.nih.gov/docs/5yearplan.htm> or via email to niceatm@niehs.nih.gov. Individuals submitting comments are asked to include appropriate contact information (name, affiliation, mailing address, phone number, email, and sponsoring organization, if applicable). All comments received will be posted on the NICEATM–ICCVAM website and identified by the individual's name, affiliation, and

sponsoring organization. Comments should be received by [insert date 60 days after publication date] to ensure consideration as the NICEATM–ICCVAM 2013–2017 Five-Year Plan is finalized.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological and safety testing methods that more accurately assess the safety and hazards of chemicals and products. ICCVAM evaluations include test methods and strategies that will reduce or replace animal use, or refine animal use by enhancing animal welfare and avoiding or lessening pain and distress.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods and strategies applicable to the needs of U.S. Federal agencies.

NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM and ICCVAM can be found on the NICEATM–

ICCVAM website (<http://iccvam.niehs.nih.gov>).

References

ICCVAM. 2008. The NICEATM–ICCVAM Five-Year Plan (2008–2012). A plan to advance alternative test methods of high scientific quality to protect and advance the health of people, animals, and the environment. NIH Publication No. 08–6410.

Research Triangle Park, NC: NIEHS.

Available: <http://iccvam.niehs.nih.gov/docs/5yearplan.htm>.

Dated: June 4, 2012

John R. Bucher,

Associate Director, National Toxicology Program

[FR Doc. 2012-14435 Filed 06/12/2012 at 8:45 am; Publication Date: 06/13/2012]